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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,316	07/13/2006	Lothar Gobel	KCX-1252-PCT-US (64355278)	7381
7590 Stephen E. Bondura Dority & Manning, P.A. P.O. Box 1449 Greenville, SC 29602			EXAMINER FLICK, JASON E	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 07/17/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,316	Applicant(s) GOBEL, LOTHAR	
	Examiner JASON FLICK	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/19/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-6 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Haber et al. (USPN 4,850,953).

3. [Claims 1-6 and 21] Haber teaches a closing system for a natural or artificial anus, comprising an inflatable thin-walled polymer (latex) balloon (figure 1, items 8 and 8'), preformed with two connection ports or ends (figure 2, items 16 and 18), having a generally toroidal structure, formed of a hose segment with a two-dimensional surface, which hose is inverted into itself, whereby its two ends extend generally coaxially with each other and are connected to a respective sleeve (feeding lumen) (figure 1, item 6); characterized in that said connection ports or ends of said balloon are preformed such that each or both of end regions of the inverted hose segment have a generally constant cross-sectional length (figures 3 and 4), wherein the two ends of the inverted hose have different lengths that correspond to different circumferential lengths of said end regions (figures 3 and 4); wherein the inverted hose is preformed such that its front end, which is distal relative to the mutually coaxial ends, assumes in an inflated state a gently curved contour with no edge regions (figures 3 and 4); and wherein said balloon is

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performed such that it has in an inflated state a diameter that exceeds a diameter of a bowel segment (figures 3 and 4).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 7 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber et al. (USPN 4,850,953).

7. [Claim 7] Haber teaches the limitations of claim 6, upon which claim 7 depends. Haber does not specifically disclose the length of the sleeve(s) is in each case smaller than one third the length of the balloon measured coaxially to the axis of symmetry of the inflated balloon. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the claimed dimensions, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

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8. [Claim 22] Haber teaches the limitations of claim 21, upon which claim 22 depends. Haber does not specifically state the balloon polymer is selected from one of polyurethane, a polyurethane/polyvinyl chloride blend and a comparable polyurethane-based material. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize such materials, since it has been held to be within the general skill of a worker in that art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

9. Claims 8-14, 16-18, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber et al. (USPN 4,850,953), in view of Kieturakis (USPN 5,667,479).

10. [Claim 8] Haber teaches the limitations of claim 6, upon which claim 8 depends. Haber does not specifically disclose the collapsed balloon is housed in a cavity. However, Kieturakis teaches a surgical resection instrument comprising a collapsible balloon (figure 3, item 40) housed in a cavity (figure 3, item 30), which is provided in a plug (figure 3, item 10) and is directed toward an interior of the bowel. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Haber with the balloon storage capability, as taught by Kieturakis, in order to provide sufficient protection for the balloon structure during insertion and removal of the system within a patient.

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11. [Claim 9] Haber and Kieturakis teach the limitations of claim 8, upon which claim 9 depends. In addition, Haber teaches that the two connection ports of said balloon are each connected by their mouths to a plug (figure 2, item 6).

12. [Claims 10 and 11] Haber and Kieturakis teach the limitations of claim 8, upon which claims 10 and 11 depend. In addition, Kieturakis discloses said plug comprises two sleeves (figure 3, items 10 and 20) that can be fitted one inside the other and in that a mouth of each connection port (figure 3, items 62 and 66) is connected to a respective one of said sleeves; wherein the mouth that is connected to an outer of the sleeves has a diameter adapted to the outer sleeve, and the mouth that is connected to the inner of the two sleeves has a diameter adapted to the inner sleeve (figure 3).

13. [Claim 12] Haber and Kieturakis teach the limitations of claim 11, upon which claim 12 depends. In addition, Kieturakis teaches the balloon can be pulled through the outer sleeve (figure 3; column 4, lines 18-26).

14. [Claim 13] Haber and Kieturakis teach the limitations of claim 11, upon which claim 13 depends. Kieturakis discloses an air channel disposed in the outer sleeve, rather than the inner sleeve (figure 3, item 41). However, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the inner sleeve, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

15. [Claim 14] Haber and Kieturakis teach the limitations of claim 13, upon which claim 14 depends. In addition, Haber teaches the air channel comprises a stop valve (figure 3, item 34).

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16. [Claims 16-18] Haber and Kieturakis teach the limitations of claim 10, upon which claims 16-18 depend. In addition, Haber discloses said plug (figure 1, item 6) and/or one or more sleeves is/are connectable to a sealing cap (figure 1, item 2), connected adjacent contact to said plug and has a folded structure.

17. [Claim 23] Haber teaches the limitations of claim 1, upon which claim 23 depends. Haber does not specifically disclose a ring-shaped element for fixing the hose element to the central lumen. However, Kieturakis teaches a surgical resection instrument comprising a ring-shaped element (figure 3, item 68) which is fixed in a central lumen (figure 3, item 44) of the hose segment inverted into itself, the fixing being effected only along a narrow, circumferentially surrounding line so as not to deteriorate the freedom of movement of the balloon. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Haber with the use of a ring-shaped fixing element, as taught by Kieturakis, in order to provide a means of securing and preventing movement of the balloon.

18. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haber et al. (USPN 4,850,953), in view of Kieturakis (USPN 5,667,479), in further view of Mulhauser et al. (PGPub 2003/0181879).

19. [Claim 15] Haber and Kieturakis teach the limitations of claim 11, upon which claim 15 depends. Haber and Kieturakis are silent on the use of a carbon filter. However, Mulhauser teaches a sealing device comprising a carbon filter which can be disposed inside the inner sleeve (figure 4, item 30; paragraph [0068]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the

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structure taught by Haber and Kieturakis with the use of a carbon filter, as taught by Mulhauser, in order to provide a means of purifying the air passing through the device.

20. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber et al. (USPN 4,850,953), in view of Kieturakis (USPN 5,667,479), in further view of Salama (USPN 6,527,755).

21. [Claims 19 and 20] Haber and Kieturakis teach the limitations of claim 16, upon which claims 19 and 20 depend. Haber and Kieturakis are silent on the use of a collection bag. However, Salama teaches a sealing device comprising a sealing cap (figure 3, item 38) and/or said plug which is connectable to a collection bag (figures 3 and 4, item 58), wherein the collection bag is connectable to said sealing cap (figure 3, item 38) and to the inner sleeve (figure 3, item 40). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Haber and Kieturakis with use of the sealing cap and collection bag combination, as taught by Salama, in order to provide a means of controlling and/or collection material flowing into or out of the device.

22. Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber et al. (USPN 4,850,953), in view of Kieturakis (USPN 5,667,479), in further view of Kim (USPN 5,569,216).

23. [Claim 24] Haber and Kieturakis teach the limitations of claim 23, upon which claim 24 depends. Haber and Kieturakis are silent on an externally controllable sealing element in the form of a separately inflatable balloon. However, Kim teaches a multipurpose sealing device comprising an externally controllable sealing element in the

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form of a separately inflatable balloon (figure 3, item 110), which is disposed in the central lumen of a hose element inverted into itself (figure 3, item 100). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Haber and Kieturakis, with the use of an additional sealing element, as taught by Kim, in order to provide a means of controlling flow through the lumen of the hose segment.

24. [Claim 25] Haber, Kieturakis, and Kim teach the limitations of claim 24, upon which claim 25 depends. In addition, Haber discloses a tube can be inserted through the central lumen of the hose segment inverted into itself (figure 4).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON FLICK whose telephone number is (571)270-7024. The examiner can normally be reached on Monday through Thursday, 7:00am to 5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F./

Examiner, Art Unit 3763

07/10/2009

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763